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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/673,926	09/29/2003	Gregory L. Sundberg	279.666US1	7372

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EXAMINER

SMITH, TERRI L

ART UNIT PAPER NUMBER

3762

DATE MAILED: 01/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Tals

<b>Office Action Summary</b>	<b>Application No.</b> 10/673,926	<b>Applicant(s)</b> SUNDBERG, GREGORY L.	
	<b>Examiner</b> Terri L. Smith	<b>Art Unit</b> 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 September 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-23 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 December 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>9-29-03</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Drawings***

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: “inner surface 184” (page 7, line 4). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office Action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the Examiner, the applicant will be notified and informed of any required corrective action in the next Office Action. The objection to the drawings will not be held in abeyance.

### ***Specification***

2. The disclosure is objected to because of the following informalities: On page 6, the sentence “For example if ... helix engages tissue” (lines 3–4) is an incomplete sentence.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1–23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 1, 8, 15, and 19 are vague. It is unclear how the fixation helix forms a drive mechanism. Does it form the mechanism simply by attaching the helix to the piston or by some other way? The Examiner is requesting the Applicant to state on the record how the fixation helix forms a drive mechanism. The Examiner has interpreted the drive mechanism as just the connection of helix to piston.

Claim 10 recites the limitation "the helical guide" in line 1. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1–3, 5–6, 8–9, 11–12, 14–21, and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Janke et al, U.S. Patent 6,097,986.

Janke discloses a lead body extending from a distal end to a proximal end (Fig. 1); a conductor disposed within a lead body (column 4, lines 55–56); a piston movably disposed within a lead body (Figs. 2A, 3A, 4A, and 5A); a piston electrically coupled with a conductor (column 7, lines 43 and 46–47) and a fixation helix supported by/coupled with a piston at a first portion/along a first longitudinal portion of a fixation helix, a first portion of a fixation helix forming a drive mechanism "(since the helix is attached to the piston)" that advances/longitudinally advances and retracts a fixation helix/rotating the fixation helix (Figs. 2A, 3A, 4A, and 5A; column 7, lines 43–50); and a guide disposed within an inner surface of a

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housing (Fig. 4A; column 7, last line—column 8, lines 1–4); a first portion of a fixation helix is coupled with a piston (column 7, lines 43 and 46–47); a piston has a recess, and at least a portion of a first portion of a fixation/active fixation helix is disposed within a recess/recessing at least a part of a first portion of a fixation helix within a piston (Figs. 2A, 3A, 4A, and 5A); a recess has a first width and a first width is less than a diameter of a first portion of a fixation helix (Figs. 2A, 3A, 4A, and 5A); approximately 1/3 to 1/2 of a diameter of a fixation helix is disposed within a recess/recessing approximately 1/3 to 1/2 of a diameter of a fixation helix within a piston (Figs. 2A, 3A, 4A, and 5A); a guide is a helical guide (column 8, lines 1–2); a fixation helix is coupled with a piston along a recess within a piston (Figs. 2A, 3A, 4A, and 5A); a fixation helix has an inner diameter and a piston has an outer diameter, and a outer diameter is greater than an inner diameter prior to coupling the fixation helix with a piston (Figs. 2A, 3A, 4A, and 5A; column 5, lines 44–45); a fixation/active fixation helix is electrically and mechanically coupled with a conductor/piston (column 3, lines 5–7 and 13–18; column 5, lines 7–10, 35–37 and 44–45).

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 4, 7, 13, and 22 rejected under 35 U.S.C. 103(a) as being unpatentable over Janke et al. as applied to claims 1, 3, 8 and 19 above, and in view of Miller, U.S. Patent 4,628,943.

Janke does not disclose a recess has a helical shape; and a housing portion disposed near a distal end of a lead body, and a guide is disposed on an inner surface of a housing portion, and a guide guides a drive mechanism; and a fixation helix is coupled with a piston along a helical recess within a piston; and recessing at least a part of a first portion of a fixation helix within a helical groove of a piston. However, Miller discloses a recess has a helical shape (Fig. 2, element 62); and a housing portion disposed near a distal end of a lead body, and a guide is disposed on an inner surface of a housing portion, and a guide guides a drive mechanism (Fig. 2, elements 44, 36, 54, 60, and 62); and a fixation helix is coupled with a piston along a helical recess within a piston (Fig. 2, elements 36, 54, 60, and 62); and recessing at least a part of a first portion of a fixation helix within a helical groove of a piston (Fig. 2, elements 36, 60 and 62) so that a sharpened distal end of the securing device can be implanted into tissue of the ventricle or atrium of a heart (column 6, lines 19–22).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Janke to include a recess has a helical shape; and a housing portion disposed near a distal end of a lead body, and a guide is disposed on an inner surface of a housing portion, and a guide guides a drive mechanism; and a fixation helix is coupled with a piston along a helical recess within a piston; and recessing at least a part of a first portion of a fixation helix within a helical groove of a piston, as taught by Miller so that a sharpened distal end of the securing device can be easily and quickly implanted into tissue of the ventricle or atrium of a heart.

9. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Janke et al, U.S. Patent 6,097,986.

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Janke teaches the limitations of claim 8 as described above. Janke does not disclose a helical guide is a segmented helical guide. However, Janke does teach that other types of guiding mechanisms can be used (column 8, lines 1-2). Therefore, Janke is capable of having a segmented helical guide for ease of directing movement of the helix during travel.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Janke to include a segmented helical guide since it is known in the art that a guide is used for ease of directing movement of the helix during travel.

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Terri L. Smith whose telephone number is 571-272-7146. The Examiner can normally be reached on Monday - Friday, between 7:30 a.m. - 4:00 p.m..

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TLS

January 3, 2006

3 January 2006

GEORGE R. EVANISKO  
PRIMARY EXAMINER

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